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RONALD E. GREIGG
GREIGG & GREIGG P.L.L.C.
1423 POWHATAN STREET, UNIT ONE
ALEXANDRIA, VA 22314

EXAMINER	
MELLER, MICHAEL V	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TOSHIYUKI BABA, HIROMASA TABATA,
KATASHI NAGAMATSU and YOSHIFUMI WATAZU

Appeal 2007-4483
Application 09/673,937
Technology Center 1600

Decided: February 27, 2008

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims. We have jurisdiction under 35 U.S.C. § 6(b). Claim 28, 35, 41, 48, and 53 are representative of the claims on appeal, and read as follows:

28. A control substance for clinical laboratory test comprising an aspartate aminotransferase, valine and medium selected from the group consisting of a serum and buffer, wherein a concentration of the valine is from 0.5 to 100 mmol/L.

35. A control substance for clinical laboratory test comprising an aspartate aminotransferase, valine, proline and medium selected from the group consisting of a serum and buffer, wherein a concentration of the valine is from 5 to 20 mmol/L and a concentration of the proline is from 10 to 500 mmol/L.

41. A control substance for clinical laboratory test comprising an aspartate aminotransferase, proline and medium selected from the group consisting of a serum and buffer, wherein a concentration of the proline is from 0.5 to 500 mmol/L.

48. A control substance for clinical laboratory test comprising an alanine aminotransferase, valine and medium selected from the group consisting of a serum and buffer, wherein a concentration of the valine is from 0.5 to 50 mmol/L.

53. A control substance for clinical laboratory test comprising an alanine aminotransferase, valine, proline and medium selected from the group consisting of a serum and buffer, wherein a concentration of the valine is from 5 to 20 mmol/L and a concentration of the proline is from 10 to 500 mmol/L.

The Examiner relies upon the following references:

Sanford	US 4,450,232	May 22, 1984
Warren	US 5,814,473	Sep. 29, 1998
De Giorgio	US 5,804,402	Sep. 8, 1998
Harada (translation)	JP 08187095	July 23, 1996
Fujio (translation)	JP 60-224498	Nov. 08, 1985

Segal et al., "Interaction of Rat Liver Alanine Aminotransferase with l-Proline," *Biochemical and Biophysical Research Communications,* vol. 30, no. 1, pp. 63-68, (1968) (hereinafter "Segal I").

Segal et al., "Some Studies on the Stability of Rat Liver Alanine Aminotransferase and on Forms of the Enzyme in Other Tissues," in *Symposium on Pyridoxal Enzymes*, pp. 37-42, (Yamada et al., eds. Maruzen Co. Ltd., Tokyo 1968) (hereinafter "Segal II").

We affirm.

DISCUSSION

Claims 28-62 stand rejected under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Th[is] is a 'new matter rejection." (Ans. 4.)

The Examiner objects to the phrase "wherein the concentration of valine is 0.5 to 50 mmol/L," asserting that while the Specification provides support for the concentration of valine being 0.5 to 100 mmol/L, it does not provide support forth in the claimed range (*id.*).

Similarly, the Examiner objects to the limitation in claim 42 that the concentration of the proline is less than 100 mmol/L, but not less than 0.5 mmol/L, asserting that the Specification only provides support for using proline at a concentration of 0.5 to 500 mmol/L (*id.*).

The Examiner asserts further that "[s]imilar problems are in claims 48 and 61." (*Id.*)

The disclosure as originally filed need not provide "*in haec verba* support for the claimed subject matter at issue," rather, the disclosure should

convey to one skilled in the art that the inventor was had possession of the invention at the time of filing. *Purdue Pharma L. P. v. Faulding Pharmaceutical Co.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000) (citations omitted).

Here, the Examiner acknowledges that Appellants have support for the broader ranges. In the absence of evidence to the contrary, one of ordinary skill would also understand that the inventors had possession at the time of filing of narrower ranges that fall within the broader ranges. As the Examiner has not provided any evidence that one skilled in the art would not understand that the inventors did not have possession of the narrower ranges, the rejection is reversed.

Claims 28-62 stand rejected under 35 U.S.C. § 103(a) as being obvious over Segal I as combined with Segal II, Harada, and Fujio, as further combined with Sanford, DeGiorgio, or Warren.

Appellants assert that the claims "should not be considered to stand or fall together." (Br. 4.) Appellants appear to argue the claims in three groups, with group I comprising claims 28-34, 41-52, 58, and 60-62; group II comprising claims 29, 48-52, 61, and 62; and group III comprising claims 35-40, 53-57, and 59. We choose claim 28 as representative of the group I claims, claim 48 as representative of the Group II claims, and claim 35 as representative of the group III claims. 37 CFR § 41.37(c)(1)(vii).

Segal I and Segal II are cited for teaching that proline at a concentration of 0.1M (100 mmol/L) stabilizes alanine aminotransferase (Ans. 4). Segal I and Segal II are also cited for teaching the use of a buffer (*id.* at 5). Segal I is additionally cited for teaching that valine at a

concentration of 0.1 M stabilizes alanine aminotransferase (*id.* at 4-5). The Examiner notes that the Segal references do not teach stabilization of aspartate aminotransferase (*id.*).

Sanford, De Giorgio, and Warren are cited for teaching that alanine aminotransferase and aspartate aminotransferase are known to be interchangeable and are used in similar ways (*id.* at 5).

Harada and Fujio are cited for teaching that the use of serums and buffers to stabilize enzymes is known in the art (*id.*).

The Examiner concludes:

> It would have been obvious to one of ordinary skill in the art at the time the invention was made to use less than 0.1 M of proline or valine since adjusting parameters to optimize the results of the invention is clearly within the purview of the skilled artisan and to adjust the amounts to the other concentrations claimed would also have been obvious since the skilled artisan uses routine experimentation to optimize the paramenters in an effort to optimize the desired results of the claimed invention. To stabilize another enzyme such as aspartate aminotransferase would have been obvious since this enzyme is so closely related to alanine aminotransferase since they are both amino acid transferases. . . .
>
> Further, to use the two amino acids together (valine and proline) would have been obvious since Segal I, teaches that valine also has a high level of stability on alanine aminotransferase. To use valine alone is also obvious since Segal 1 uses valine alone to test the stability of the enzyme and yields a high result.

(*Id.*)

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the

claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 1739.

As to the Group I claims, Appellants do not appear to present any arguments. Claim 28 is drawn to control substance for clinical laboratory test comprising an aspartate aminotransferase, valine and medium selected from the group consisting of a serum and buffer, wherein a concentration of the valine is from 0.5 to 100 mmol/L. The Segal references teach a concentration of valine of 100 mmol/L to stabilize alanine aminotransferase, and Appellants admit that aspartate amino transferase and alanine aminotransferase are used interchangeably in clinical setting (Br. 8). Thus, the rejection is affirmed as to the claims of Group I.

As to the Group II claims, claim 48 representative, Appellants argue that Segal I teaches using proline and valine separately at a concentration of 100 mmol/L (Br. 8). Claim 48, Appellants assert, recites that valine is used at a concentration of 0.5 to 50 mmol/L, which is not taught by Segal 1, and that none of the other references cited by the Examiner remedy that deficiency (*id.* at 9).

Appellants' argument is not convincing. Segal I teaches that the ability of valine to stabilize alanine aminotransferase was measured at a

concentration of 0.1M (100 mmol/L) (Segal I, p. 39, Table 1). Segal I does not teach that the concentration is critical. Determining the optimum values of a result effective variable, such as the concentration of valine required to stabilize a solution of alanine aminotransferase, is ordinarily within the skill of the art. *See In re Boesch*, 617 F.2d 272, 276 (CCPA 1980). Note that a "person of ordinary skill is also a person of ordinary creativity, not an automaton." *KSR*, 127 S. Ct. at 1742. Thus, the rejection is affirmed as to the Group II claims.

As to the Group III claims, claim 35, Appellants argue that Segal I does not teach using valine and proline to stabilize the same solution, nor do any of the other references cited by the Examiner (Br. 8). Appellants argue further that Segal I does not teach the recited concentration of valine, and none of the other references cited by the Examiner remedy that deficiency (*id.* at 9).

As Segal I teaches that both valine and proline stabilize alainine aminotransferase, it would have been obvious to the ordinary artisan to use them together in a solution to stabilize the enzyme. This type of motivation has been recognized often by the predecessor of our reviewing court, which has held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the same purpose. *In re Susi*, 440 F.2d 442, 445 (CCPA 1971); *In re Crockett*, 279 F.2d 274, 276-77 (CCPA 1960). The idea of combining them flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Here the art recognized enzyme stabilizing properties of each of the described agents would have

provided one of ordinary skill in the art with ample suggestion of their combination in the composition as claimed. *KSR*, 127 S. Ct. at 1739 ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

As to the concentration of valine recited in claim 35, as explained above with respect to the Group II claims, determining the optimum values of a result effective variable, such as the concentration of valine required to stabilize a solution of alanine aminotransferase, is ordinarily within the skill of the art.

CONCLUSION

In summary, we reverse the rejection of claims 28-62 under 35 U.S.C. § 112, first paragraph, as containing new matter. As we conclude, however, that the Examiner has set forth a *prima facie* case of obviousness, the rejection of claims 28-62 under 35 U.S.C. § 103(a) as being obvious over Segal I as combined with Segal II, Harada, and Fujio, as further combined with Sanford, DeGiorgio, or Warren, is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

RONALD E. GREIGG
GREIGG & GREIGG P.L.L.C.
1423 POWHATAN STREET, UNIT ONE
ALEXANDRIA VA 22314

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